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WE CLAIM:

1. A recombinant or synthetic peptide or chemical equivalent thereof comprising the formula:

 $X_1X_2X_3$

wherein:

X₁ and X₃ may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X₂ is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM).

- 2. A peptide molecule according to claim X_2 wherein X_2 comprises from 10 to 50 amino acid residues.
- 3. A peptide molecule according to claim 2 wherein X_2 comprises from 10 to 30 amino acid residues.
- 4. A peptide molecule according to claim 3 wherein X_2 comprises from 10 to 15 amino acid residues.
- 5. A peptide molecule according to claim 1 or 2 or 3 or 4 wherein X_2 comprises the amino acid sequence: FFYTPKTRREARD.
 - 6. Speptide molecule according to claim 1 or 2 or 3 or 4 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLEDSED ID.2)

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7. A recombinant or synthetic peptide or chemical equivalent thereof comprising the sequence:

 $X|X_2X_3$

wherein:

X₁ and X₂ may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X₂ is selected from FFYTPKTRREAED and FWYIPPSLRTLED or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical IDDM.

8. A method of assaying the reactivity of a subject to IDDM autoantigen said method comprising contacting a peptide or chemical equivalent thereof comprising the formula:

 $X_1X_2X_3$

wherein:

X₁ and X₃ may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X₂ is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM) with cells from said subject and determining reactivity by an appropriate assay.

- 9. A method according to claim 8 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.
- 10. A method according to claim 8 or 9 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

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- 11. A method according to claim 8 wherein X_2 comprises from 10 to 50 amino acid residues.
- 12. A method according to claim 11 wherein X_2 comprises from 10 to 30 amino acid residues.
- 13. A method according to claim 12 wherein X_2 comprises from 10 to 15 amino acid residues.
- 14. A method according to claim 8 or 9 or 10 or 11 or 12 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED.
- 15. A method according to claim 8 or 9 or 10 or 11 or 12 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED.
- 16. A method of assaying the reactivity of a subject to IDDM autoantigen said method comprising contacting a peptide or chemical equivalent thereof comprising the formula:

 $X_1X_2X_3$

wherein:

 X_1 and X_2 may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X_2 is selected from FFYTPKTRREAED and FWYIPPSLRTLED or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with preclinical or clinical IDDM with cells from said subject and determining reactivity by an appropriate assay.

17. A method according to claim 16 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.



- 18. A method according to claim 16 or 17 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.
- 19. Use of a peptide or chemidal equivalent thereof comprising the formula:

 $X_1X_2X_3$

wherein:

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X₁ and X₃ may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X₂ is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM) to assay reactivity of a subject to IDDM autoantigen by contacting said peptide or its chemical equivalent to cells from said subject and determining reactivity by an appropriate assay.

- 20. Use according to claim 19 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.
- 21. Use according to claim 19 or 20 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.
- 22. Use according to claim 19 wherein X_2 comprises from 10 to 50 amino acid residues.
- 23. Use according to claim 22 wherein X_2 comprises from 10 to 30 amino acid residues.

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- 24. Use according to claim 23 wherein X_2 comprises from 10 to 15 amino acid residues.
- 25. Use according to claim 19 or 20 or 21 or 22 or 23 or 24 wherein X_2 comprises the amino acid sequence: FFYTPKTRREAED.
- 26. Use according to claim 19 or 20 or 21 or 22 or 23 or 24 wherein X_2 comprises the amino acid sequence: FWYIPPSLRTLED.
- 27. Use of a peptide or chemical equivalent thereof comprising the formula: $X_1X_2X_3$

wherein:

 X_1 and X_2 may be the same or different and each is an amino acid sequence comprising from 0 to 15 naturally or non-naturally occurring amino acid residues; X_2 is selected from FFYTPKTRREAED and FWYIPPSLRTLED or a derivative or chemical equivalent thereof and wherein said peptide is capable of reacting with T cells and modifying T-cell function when incubated with cells from subjects with preclinical or clinical IDDM to assay reactivity of a subject to IDDM autoantigen by contacting said peptide or its chemical equivalent with cells from said subject and determining reactivity by a proliferation assay.

- 28. Use of a peptide or chemical equivalent according to claim 27 wherein the cells are selected from the group comprising PBMCs, anti-coagulated whole blood and/or tissue biopsy cells.
- 29. Use of a peptide or chemical equivalent according to claim 27 or 28 wherein an appropriate assay includes proliferation assay, cytotoxic assays, celular reactivity or combination thereof.

30. A method of treatment comprising administering to a subject an effective amount of a peptide or chemical equivalent thereof for a time and under conditions sufficient to remove or substantially reduce the presence in said subject of autoreactive T-cells and/or autoantibodies to IDDM autoantigens wherein the peptide comprises the formula:

 $X_1X_2X_3$

wherein:

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X₁ and X₃ may be the same or different and each is an amino acid sequence comprising from 0 to 40 naturally or non-naturally occurring amino acid residues; X₂ is any amino acid sequence of from 10 to 100 residues derived from, homologous to or contiguous within amino acids 506 to 518 inclusive or derivatives thereof of human GAD65 and/or amino acids 24 to 36 inclusive or derivatives thereof of human proinsulin; and wherein said peptide molecule is capable of reacting or modifying T-cell function when incubated with cells from subjects having pre-clinical or clinical Insulin-Dependent Diabetes Mellitus (IDDM).

- 31. A method according to claim 30 wherein X_2 comprises from 10 to 50 amino acid residues.
- 32. A method according to claim 3) wherein X_2 comprises from 10 to 30 amino acid residues.
- 33. A method according to claim 32 wherein X_2 comprises from 10 to 15 amino acid residues.
- 34. A method according to claim 30 or 31 or 32 or 33 wherein X₂ comprises the amino acid sequence: FFYTPKTRREAED FOR LOW!
- 35. A method according to claim 30 or 31 or 32 or 33 wherein X₂ comprises the amino acid sequence: FWYIPPSLRTLED.

36. A pharmaceutical composition comprising a recombinant peptide or equivalent thereof according to claim or 7 and one or more pharmaceutically acceptable carriers and/or diluents.

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